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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,174	06/08/2006	Keiichi Fujiwara	0020-5490PUS1	8923

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EXAMINER	
HUANG, GIGI GEORGIANA	
ART UNIT	**PAPER NUMBER**
1612	

NOTIFICATION DATE	DELIVERY MODE
12/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/582,174	FUJIWARA ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6-11 and 13-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6-11 and 13-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/28/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The response filed August 22, 2008 and September 22, 2008 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claims 1, 10, 13-14, 17-20 have been amended.

   b. Claim 12 has been cancelled.

   c. Claim 22-23 has been added.

2. Claims 1, 4, 6-11, 13-23 are pending in the case.

3. Claims 1, 4, 6-11, 13-23 are present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. All grounds not addressed in the action are withdrawn or moot.

6. New grounds of rejection are set forth in the current office action.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebert et al. (U.S. Pat. No. 6368625).

Siebert et al. teaches an oral disintegrable dosage form comprising an active ingredient, sugar or sugar alcohol, binders, disintegrants, and other excipients. The dosage form can be a microgranule, granules, particles, microparticles, powder, tablets, and capsules. The active include pharmaceutical ingredients and the formulation is particularly capable of taste masking distasteful drug particles. The sugar or sugar alcohol preferably includes mannitol. The binders preferably include microcrystalline cellulose, starch, and methyl cellulose. Desirable disintegrants include crospovidone. Example 1 is a powder (granular) composition comprising famotidine, mannitol, microcrystalline cellulose (Avicel), and crospovidone that is formed into a tablet. The ratios for famotidine, mannitol, and binder are based on the amounts of each component. The amount of water is negligible as it is evaporated during granulation. There is 9.09mg of famotidine, 30mg microcrystalline cellulose, and 151.1mg mannitol in the tablet. The ratio of famotidine to the binder is 9.09:30 or 1:3.3. The ratio of binder to mannitol is 30:151.1 or 1:5.04.

The disintegration properties and profiles are intrinsic to the composition. When the components of compositions are met, the properties related to it are the same. The composition is prepared by creating a coating solution (water-containing solvent comprising ethyl cellulose and HPMC-both binders), the drug (famotidine), is screened, coated while granulated, blending with mannitol, binder, disintegrant, other excipients, screened, mixed, powder is discharged, then tableted.

Siebert et al. does not expressly teach methylcellulose in the example or expressly a granule form.

However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute methylcellulose for microcrystalline cellulose, as suggested by Siebert, and produce the instant invention. Siebert teaches that the preferred binders include microcrystalline cellulose and methyl cellulose. It would have be obvious to one of skill in the art to substitute one preferred binder for another depending on availability or desired properties as they are taught to be analogous. It is also obvious to form granules as taught by Siebert (forms taught include granules, particles, microparticles, powder, tablets) with the formulations presented such as in Example 1 by granulation with the same granulation process taught by Siebert in Example 1 with the same aqueous solvent presented (water with binders), as it is within the skill of one in the art and these minor variations are routinely practiced in the art to determine the best therapeutic efficacy and profile for the best outcome in the final product.

One of ordinary skill in the art would have been motivated to do this because it is desirable for manufacturers to have analogous choices to substitute the binders when motivated by pricing, availability, or desired properties of the binder used to produce the final product. It is also desirable to have different forms of the same product for different modes of delivery dependent on the profile desired.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have

had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

9. Claim 1, 4-7, and 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebert et al. (U.S. Pat. No. 6368625).

Claim 12 is cancelled, the rejection is moot.

Applicant's arguments filed 9/22/2008 have been fully considered but they are not persuasive. Applicant asserts that the “particle” is an “intermediate” form compared to a “final" form. As the “particle” in the specification on page 21, can further comprise additional excipients and is a solid form, it is viewed as the same as a granule or powder with the same components which are forms taught by Siebert that can be formed from the formulations taught including Example 1. There is no distinguishing difference in the composition between the forms. The art meets the composition recitations of the claims. The recitation of intended use for taste does not have patentable weight in a composition claim. The amended ratios are still met.

Accordingly, the rejection is maintained.

10. Claims 8-10, 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebert et al. (U.S. Pat. No. 6368625) as applied to claims 1, 4-7, 11-20 above, in view of Depui et al. (U.S. Pat. No. 6132771) and further in view of Yoshinari et al. (U.S. Pat. No. 6235947).

Applicant's arguments filed 9/22/2008 have been fully considered but they are not persuasive. Applicant's argument is to Depui and Yoshinari with respect to mosapride and D-mannitol to a particle whereby the references were used in the action to address analogous drugs and substitution of mannitol with D-mannitol for its improved properties. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.

Accordingly, the rejection is maintained.

Conclusion

11. Claims 1, 4, 6-11, 13-23 are rejected.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612